A I'm checking that now. It's taking time. They've got cross-outs on here. I mean, this is not a good analytical sheet. The numbers are good. But if I were training an analytical chemist I'd say you don't cross the number out and not put your initials and the date on there. That's what I'm looking at right there.

Q Regardless of whether you like Celsis Analytical Labs' methods, did the three samples pass?

A It was just distracting to me. But the three samples, samples, passed, yes.

Q Okay. Had you ever seen that document before?

A No.

Q Here's Exhibit 69. Have you ever seen this before?

A I'm only on the first page, but my answer is no.

Q Okay. I will represent to you that Exhibit 69 represents UDL documents concerning the testing of Digitek Lot 80111A and that it passed the tests to which it was subjected. Am I correct?

A This .25 milligram dose, yes, you are correct.

Q All right. I'm showing you Exhibit 70. Have you ever seen that before?

A I believe I have not seen that before.

Q I will represent to you that that's UDL documents about the testing of Digitek Lot 71034A and that the samples passed the test to which they subjected it. Am I correct?

MR. KERENSKY: You read 71034A and there appears to be a 1 after the A.

MR. MORIARTY: Correct.

MR. KERENSKY: You didn't say the 1.

Q Okay. Well --

A I heard your question. I'm looking up the data to tell you if they did pass. Yes, they do pass. The sample passed.

Q I'm handing you Exhibit 71. Have you ever seen it before?

A I believe not.

Q I will represent to you that Exhibit 71 is the UDL documents concerning their testing of Digitek Batch 71004A1 and that the Digitek passed all the tests to which they subjected it. Am I correct?

A Yes. I'm looking at what tests were done. That's why I'm pausing. Yes.

Q I'm showing you Exhibit 72. Have you ever seen that document?

A I believe I have not.

Q I will represent to you that it is UDL's documents regarding the testing of Digitek Lot 70175A1 and that the Digitek passed the tests that they -- to which they subjected it. Am I correct?

A I'm looking. Yes, you are correct.

Q Okay. Now, are you aware that UDL, one of the things that they did was to re-package Digitek from bottles to blister packs?

A I was not aware it was UDL who did that.

Q But you know it happened at some distributor level?

A Yes.

Q And do you know for a fact from any documents you've reviewed or any depositions you've read whether tablets that were double their intended thickness would have fit into UDL blister packs for Digitek?

A I don't know the answer as to whether they would or would not.

Q Would it be important for you to know the answer to that question?

A I believe it would certainly be, yes, nice to know.

Q Because if UDL never rejected any Digitek tablets as double thick, that would be some scientific

information about consistency of the thickness of the product, correct?

A It would. I would have to see their records as to whether they rejected any. I would have to see their method of packaging to determine if -- what system they used to reject anything that was too large or too small.

Q Do you know whether the UDL thickness specifications for the product were even tighter than the Actavis specifications?

A I don't know that.

THE VIDEOGRAPHER: It's time to make a tape change, sir.

MR. MORIARTY: I'm sorry?

THE VIDEOGRAPHER: I have to make a tape change. We are off record at 11:28. Just one moment. Pause, please.

(Off the record.)

THE VIDEOGRAPHER: All right. We're back on record. This is the beginning of Tape No. 3 in the Farley deposition.

BY MR. MORIARTY:

Q From your knowledge of the way that FDA looks at things, if UDL re-packaged Digitek from bottles to blister packs, would UDL be required to test for

stability on the product in order to assure that the change in packaging didn't change the shelf life of the drug?

A If you have a contact surface area of the plastic to use to generate current against there, somebody would be required to test for stability because of the contact with the drug product.

Q Have you ever seen any records from UDL regarding the results of stability testing for Digitek?

A No.

Q When they test for stability do they test for assay typically?

A Among others, but that would definitely be it.

Q Would they typically do content uniformity? Or I'm sorry. Let me withdraw that.

Would they typically also do dissolution?

A For tablets would they typically? Usually, not invariably, but most times. Typically was your word. Let's use that. Yes.

Q To your knowledge did any Digitek batch ever fail stability under any UDL program?

A I don't know the answer to that.

Q Would that be important information for you to know?

A It would be.
Q And if you assume that no Digitek batch ever failed stability under a UDL program, does that speak to the consistency of the quality of the product?
A If I saw the stability protocol and if I saw the method they used and agreed that it was a good method and if I knew it was a well-trained person conducting it, everything that would give credibility to the results, then, yes, it would.
Q And no one has submitted any of that kind of data to you for review in this litigation, correct?
A I believe they did not.
Q And you have no reason to believe that FDA has questioned the testing methods of UDL, correct?
A Correct.
Q If -- have you been supplied any information about testing on Digitek done by NMS Labs from your previous home area of Philadelphia?
A No.
Q Are you familiar with NMS Labs?
A No.
Q If anybody ever presented you with testing information about Digitek would you want to look at their methodology and validation before you drew any conclusions about the validity of the testing?

A That and more. The reputation of the company, something about the training of the analysts who were running it. Everything you said and more.

Q Okay. Now, my colleague, Mr. Anderton, already asked you some questions about the regulatory definition of adulteration. And I don't want to repeat those questions, but I have a follow-up.

Have you ever seen any peer reviewed scientific literature, any FDA statements or any other kind of scientific statement which says in words or effect that the regulatory definition of adulteration means that there was out-of-specification product in fact either made or distributed?

A You're getting to like within the definition of adulteration? Is that -- am I reading your question properly or am I not?

MR. ERNST: Objection to form.

Q I thought the question was plain. If you don't understand it I'll be happy to rephrase it.

A Okay. Just one more time. Let me see if I get it this time.

Q Okay. All right. Let me go back. All right. Mr. Anderton asked you about Exhibit 39. Okay?

A I forget what one that is offhand but --

Q I'm handing you from the original stack

what Exhibit 39 is. Okay?

A Yes. I see it.

Q And this is the statement from the FDA's own Web site, Facts About Current Good Manufacturing Practices, correct?

A It looks like it is.

Q And about halfway down there's a bolded question that says, If a manufacturer is not following CGMPs are drug products safe for use.

Do you see that?

A Yes.

Q And then it basically gives the statement that if a company is not complying with CGMPs it makes the drug adulterated under the law.

Do you see that?

A Yes.

Q The last sentence of that paragraph says, It does not mean that there is necessarily something wrong with the drug.

Do you see that?

A Yes.

Q Okay. Now, what I want to know from you is whether you have any peer reviewed literature or an FDA statement or some other scientific statement contrary to what the FDA is saying in its Web site in

Exhibit 39.

A Stating --

Q First a yes or no and then you can explain.

A Do I have any evidence of anyone who directly contradicts that?

Q That's basically what I was asking you.

A I do not.

Q Okay. Now, did you want to explain your answer?

A Yes.

Q Go ahead.

A When there's a violation of GMPs it is implied or understood in the industry or generally accepted there is a likelihood that an improper harmful -- potentially harmful product is being released to the public.

It, as you say, is not a guarantee, but there's a likelihood that there's a, quote, bad product getting out to the market if in fact it was released.

So while there's no direct contradiction here as you asked, it's the general thinking among people in the industry and FDA you didn't comply with GMPs, there's a likelihood of a problem with this material.

Q Okay. Let me ask you about that. Does

every finding of adulteration lead to a recall?

A No.

Q Well, if you are correct that there is a likelihood that bad product is out, how come it isn't recalled?

A It's a combination of factors. It depends on the product itself. If it's a drug, how sensitive is that drug. In this case it's therapeutic index. A person might get harmed. It's who's taking it. There's a whole variety of factors that go into the determination to do a recall or not.

Q But you told me that every time there's an adulteration there's a likelihood that bad product got out. Okay? So where in the FDA rules, regs, interpretations, field manuals does it give this sort of rule that you just said that there's a likelihood but it all depends? Where is it?

A In the regulations where it says there's a likelihood?

Q Yeah. Where in the regs, where in a piece of scientific peer reviewed literature, where in a manual anywhere that I can go read to check on what you just told me?

A It says it's an adulterated product. Since it's an adulterated product it has not been made

the way it should have been made and will quite likely, quite likely, not be of the identity, strength, quality and purity they say that it is purported to be and in -- it could be harmful.

Q Well, does the definition of adulteration in the regulations say that? Does it use the word likely?

A I read it somewhere and I'm at a loss to quote it now. I don't know if I read it in the regulations or some document but -- or whether I heard it at meetings at the FDA. I don't know.

Q I'm asking you a question of whether the regulation itself that defines adulteration --

A Yes.

Q -- uses the word likely.

A I do not know if it does or doesn't offhand. I would have to read that regulation. I'm not saying it does; I'm not saying it doesn't. I just don't know.

Q So let me get back to my basic question. Can you cite for me a piece of peer reviewed literature, a regulation, a manual, any piece of scientific information that indicates that adulteration means that there is a likelihood that bad product actually made it to the market?

MR. ERNST: Objection to form.

A It means by definition --

Q Wait. Answer my question, please, and then you can give your explanation.

MR. ERNST: Objection to form. You haven't asked a question.

A I thought I was trying to answer your question. Can I try that again to see --

Q Sure.

A It means you didn't make it the way you said you would make it, and therefore, it is not exactly what you said it would be.

Q Isn't it in fact just possible that it's not what you said it would be?

MR. ERNST: Objection to form.

A The way we would think when I was at FDA, the thinking that's engrained into you is, you didn't make it the way you said, therefore it isn't what you want it to be.

Q Okay. I'm asking you, but isn't it just possible that it's not what you want it to be as opposed to likely?

MR. ERNST: Objection to form.

A Getting into possible, likely, probable, that depends on who you ask.

Q I'm asking you under oath today as an expert in the Digitek litigation. Okay? You can't point me to anything in the regs or any other scientific writings that support what you're saying.

So I'm asking, isn't it in -- a fact that when there is an adulteration by definition under the FDCA, that it only means it's possible that bad product actually got out?

MR. ERNST: Objection to form.

A Now, if you're asking me how I would feel about it, if you put a medication in front of me like Lipitor that I take and said this is a -- this is a generic firm made this, but it wasn't made according to GMPs, take it, Jim, and save a few bucks, I would say, I don't want to take that, because in my mind there's a likelihood that something is wrong with that.

Q So that's your personal opinion?

A That's -- that's the opinion I just gave. I wouldn't take it if someone said this is -- this would save you a couple bucks, but it's not made according to GMPs. I wouldn't.

Q Okay. So that's why in your article that we asked you about before you actually want to test it to see if it is or isn't, right?

A I would want to test it to see the final

product, assay, everything. But I also want to know it's made according to GMPs.

Q Well, that's -- anything in Exhibit 39 in the FDA's own Web site that says that it's likely that the product that got out was in fact bad?

A I don't see the word likely.

MR. ERNST: Form.

Q Did your co-author, Mr. Brooks, in your article that you guys wrote cite any law or regulations to say that it's likely that defective product is out there when it's adulterated?

A I don't actually remember whether we did or not. I don't. It was over two years ago we wrote that.

Q Okay.

MR. MORIARTY: Does it smell to anyone else in here like there is something burning?

THE VIDEOGRAPHER: Do you want to go off record?

MR. MORIARTY: Yeah.

THE VIDEOGRAPHER: We're off record. The time is 11:44.

(A brief recess was taken.)

THE VIDEOGRAPHER: We're back on record, 11:44.

MR. MORIARTY: Okay. Let's go back on the record.

BY MR. MORIARTY:

Q Have you ever seen any Actavis documents from either blend uniformity testing or finished product testing that show out-of-specification results for Digitek?

A Out-of-specification with regard to double thickness?

Q Or normal size, too much API, other than the 20 tablets in 70924.

A Other than that?

Q Yeah.

A I was going to say what I've seen is those documents and I didn't --

Q And the assays?

A -- see those results on them. I have not seen anything since then.

Q Okay. Let's go back to this statement about likelihood or not likelihood. Okay? This goes here. This is Exhibit 38. It's another statement from the FDA's Web site called Facts and Myths About Generic Drugs.

A I see it.

Q On the second page near the top it says

Myth, There are quality problems with generic drug manufacturing. A recent recall of generic Digoxin, called Digitek, shows that generic drugs put patients at risk.

And then it says Fact, FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs, generic and brand name, are held.

Do you see that?

A I do.

Q All right. In the fourth bullet point it says, In our best judgment given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.

Do you see that?

A The fourth bullet point?

Q Yes, sir.

A I see it but I'm questioning the FDA putting that on their Web site. I'm not doubting what you put in front of me, but I'm questioning their mentality when they put that out there, because they don't usually get specific.

And I think when Mr. Anderton presented this I said the same thing. I said they don't usually go into

brand names. And it's very much of a surprise. But, yes, I see what you put in front of me.

Q All right. Other than 483s and warning letters what documents have you seen to indicate that it is likely that there was defective Digitek in the hands of any consumer?

A Consent decree.

Q Anything else?

A A consent decree is a big deal. That's a big --

Q Can consent decree say -- even have the word Digitek in it?

A It essentially said, my words, we don't think you're capable of making anything right; therefore, you need a third party to help you make it.

Q Okay. So you've seen all this Celsis Labs testing.

A No.

Q You've seen the FDA's testing.

A This morning.

Q And you haven't even looked at any Actavis batch records other than 70924. So other than the FDA's regulatory documents what have you seen to indicate to you that there is any likelihood of out-of-spec Digitek in the hands of any consumer?

A It sounds to me like you're minimizing the significance of a 483 or a warning letter.

Q No, sir.

A They are serious things.

Q What I'm trying to ask you -- I'm trying to understand your opinions and the support for your opinions.

A Yes.

Q I understand what you relied on, those three categories. I want to know if there's anything else. Okay? You've said warning letters, 483s and a consent decree. Anything else?

A And the double thick tablets that were found and not analyzed, which is surprising.

Q I'm -- maybe you're missing the question.

A I might be.

Q Okay? I want to know any documents that indicate to you the likelihood that out-of-spec Digitek made it to the hands of consumers, okay, hands of consumers, not rejected at the plant.

A Separate from my feeling that there was a good possibility that some might, I haven't seen a document that indicated that there was. But what I'm looking at is not the quantity.

You could show me a hundred more analytical

results of a bottle here and a bottle there. But when I take the few 483s and couple of warning letters and I look at what was wrong with that place, I realized the sampling was a very small amount. And I would not have confidence in taking any medication that they produced.

Q Okay.

A So that's a lengthy answer, but I want to put it in a proper perspective for all of us.

Q If a client hired you to analyze this, you would look at the actual records, the manufacturing records, the testing records, things of that nature. You would actually want the detail, not just the broadbrush of the 483s, correct?

A Including the methods and the training, all of the above.

Q All right. Did you review any annual data reviews or annual reports?

A I did not. I believe I did not.

Q Do you know that has summaries of all of the testing, finished product testing --

A Yes.

Q -- for every batch?

A Yes.

Q Now, the ANDA -- you know what that is, right --

A It's the Abbreviated New Drug Application for generic.

Q -- contains a -- have you seen the ANDA for Digitek?

A The actual ANDA?

Q Yeah.

A No.

Q I mean, a copy of it?

A No.

Q Well, you know that the ANDA has a product formula, does it not?

A Yes.

Q It lists the ingredients and the amount of an ingredient?

A Yes.

Q And you know that formula was approved by FDA?

A Yes.

Q And do you know typically in the manufacturing process that raw materials, including the API, are weighed at the beginning of each batch to assure that the proper amount is put in that complies with the formula?

A Yes.

Q Do you know that from review of any batch

records that when they are blended one person verifies it and it's verified by a second person that the blending is done properly?

A Yes. I only reviewed the one batch record and in that one I found that the same person checked his or her own work, which is sacrilegious, one might say.

Q In the blend?

A In -- somewhere along the way. I forget offhand. I'd have to review the batch record again to answer that. But I found -- in effect I'm saying I found a flaw in it and that flaw was a person checking his or her own work, same initials on the left side and right side of the sheet, which is a violation right there.

Q Have you seen any citations, warnings or sanctions from the FDA upon Actavis for not following the Digitek formula that was set out in the ANDA?

A No.

Q Did Actavis keep raw material inventory cards?

A I do not know that. They should. They're supposed to.

Q Have you ever seen anything to indicate that Actavis was using Digitek components at rates inconsistent with their batch production?

A No. I saw they were not cleaning the materials properly, the equipment, between batches, which cause concern. But your question referred to the proper amounts, I believe, and my answer is no.

Q My questions are relatively specific and direct.

A Okay.

Q If you can just answer mine --

A Okay.

Q -- not some other. I didn't ask you about cleaning validation or anything else.

A Yes.

Q I asked about inventory.

A Yes.

Q Okay? Have you ever seen evidence of an FDA citation, warning or observation that Actavis was using too much Digoxin as tested at the blend uniformity stage?

A No.

Q Do you know that periodically tablets are tested by QA and production during manufacturing for hardness, thickness and weight?

A Yes.

Q Do you know that those sampling plans were approved by the FDA?

A I didn't see them, but I would have to assume they were.

Q Have you ever seen any FDA citation, warning or observation to indicate that Actavis was not following its FDA approved sampling plans?

A I'm reflecting on the 483s as I'm formulating my answer. I'm trying to think if sampling plans were in the 483s. My answer is no.

Q Do you know how many out-of-specification results occurred of the 270 Digitek batches made between 2003 and 2007 during production for weight, thickness or hardness?

A I do not know.

Q Now, from a manufacturing and quality standpoint is there a difference between a double thick tablet and a normal sized tablet with too much active pharmaceutical ingredient?

A Is there a difference?

Q Yeah.

A The very fact it's double thick is the difference. I need a little more information --

Q Sure.

A -- on the question. I'm not getting it.

Q Well, I know you're not a manufacturing expert. But in fact, is the root cause of a double

thick tablet different from the root cause of a normal sized tablet that has too much active pharmaceutical ingredient?

A It can be.

Q Do you think the FDA knows the difference between a double thick tablet and a normal sized tablet with too much active pharmaceutical ingredient?

A They should.

Q Did you ever see any citations, warnings or observations to indicate that Actavis was manufacturing Digitek normal size but too much active pharmaceutical ingredient?

A I did not see much analytical data at all and I did not see anything to that effect.

Q I'm not asking you about analytical data. I'm asking whether you saw any FDA observations, citations or warnings to indicate that Actavis was making Digitek normal size but with too much active pharmaceutical ingredient.

A No.

Q And the FDA approved recall notice didn't say anything about normal size tablets with too much API, did it?

A Correct.

Q If FDA was concerned about the specific

problem of normal sized tablets with too much API, do you think they would have had Actavis say something about that in the recall notice?

MR. ERNST: Objection to form.

A I'm thinking whether they would have tested it first or got the recall out first. I believe they would have said something about it, tell the reason for the recall.

Q And they probably would have said something about it in Exhibit 38 on their Web site when they specifically talk about Digitek and the recall a year and a quarter after the recall had occurred, correct?

A I can't predict what they would or would not because I'm not in agreement with the way they formulated this in the first place.

Q Well, if information had come to the FDA's attention even post-recall that there was a problem with normal sized tablets and too much active pharmaceutical ingredient in them, don't you think they would have said something in Exhibit 38 about that?

A I don't know. I can't predict what they would or wouldn't put on there. I really can't answer that. I don't know who can.

Q Well, if you worked for the FDA wouldn't

you say something about that?

A I think the answer to that you'd have to ask Dr. Margaret Hanburg. She's the commissioner.

Q Were the finished product testing plans approved by FDA?

A They should have been.

Q Were they in every batch record?

A Should have been.

Q Did FDA have every opportunity to inspect and comment upon those testing plans between 2004 and 2008?

A I don't know what the inspectors had on their agendas when they left the office to go and inspect. I can't speak for that. I'd be happy to read the minds of the ladies who did the inspections.

Q I'm not asking whether they had it on their agenda, Mr. Farley. I'm asking whether they had the batch records available for review when they did their inspections.

A They could request the batch records at any time. So in that regard it would be available for review if they felt they needed the batch records.

Q And if they were suspicious about Actavis' finished product testing program do you think it likely that the inspectors would have looked at those?

A About Actavis' finished product testing program --

Q Yes.

A -- is it likely -- we get into this word likely. It is possible they may have.

Q No. So you think if FDA was concerned about Actavis' finished product testing that it's only possible they would have looked at batch records?

A At that time when that inspection when they're finding deviations, out-of-specification results, things not being documented, they had their hands full with all the other violations.

And they might have gone back to the district and said, I need a couple other people to come with me next week. I'm assuming you mean that day are they going to ask for it.

Q No. At some point they would have gotten to it, right?

A At some point? They may have gotten to it depending on the personnel -- they had their hands full with all of the violations in the first place.

Q At some point it's probable they would have gotten to it, right?

A Possible.

Q Okay. Did FDA ever cite, warn or observe

that Actavis was not following its finished product ANDA procedures for Digitek?

A ANDA procedures? Could you explain that more?

Q The ANDA sets forth the finished product testing procedures, doesn't it?

A I didn't hear you say finished product testing. I'm sorry.

Q And it's FDA approved, correct?

A Yes.

Q Did FDA ever cite, warn or observe that Actavis was not following its finished product testing procedures regarding Digitek?

A Procedures that Digitek proposed and FDA said, okay, they're good, do it? No, I did not see that.

Q When we say finished product testing procedures, we're on the same page. We're talking about assay, dissolution and content uniformity, correct?

A From what I've read here this morning, finished product testing is testing on the product as it leaves to go to the next consumer.

Q Do you know what kind of testing it is?

A I'm sorry. Say again?

Q Do you know what kind of testing they do?

A From what I read this morning -- I know what they should do normally, but I know more specifically from what you showed me this morning.

Q Well, when you read Batch 70924's records did you look at the kind of testing Actavis subjected the product to?

A Yes.

Q And it was assay, dissolution and content uniformity, correct?

A Yes.

Q Okay. Did FDA ever cite Actavis or observe that Actavis had out-of-specification stability results for Digitek?

A They cited them for not taking samples at the prescribed time that was in their stability protocol. Therefore, they found a flaw in the program. So when you have a flaw in the program and then you say did I have out-of-spec samples, it's a tough one to answer because you aren't taking all the samples you were supposed to take.

Q Okay. I'm just asking, did they ever cite, observe or warn Actavis for out-of-specification stability samples? Yes or no?

A For out-of-specification stability samples? No.

Q Or content uniformity?
A No.
MR. MORIARTY: How much time on the tape?
THE VIDEOGRAPHER: The time on the tape left is 25 minutes.
MR. MORIARTY: Okay.
BY MR. MORIARTY:
Q Let me see if I can put a question to you a different way. You've -- you've seen the 484s. You've seen the Celsis and UDL testing. I want you to assume that the batch records for Digitek show consistent production within the specifications. Okay?
A Yes.
Q I want you to assume that.
A We'll do that.
Q All right. Are you -- do you intend to tell a jury that Actavis was in fact producing defective Digitek and it's just shear coincidence that none of that defective product was discovered by Actavis, FDA, UDL or Celsis?
A I do not intend to tell anybody that because I don't know that. I was -- I don't have confidence they're capable of making a quality product even though they got good analytical results on what is an extremely small percentage of sampling.

But I can't say they made bad stuff. I say in my mind I believe there's a likelihood, in my mind, a likelihood that there could be bad material on the market.

Q Okay.

A Can I clarify that more for my own mind, too?

Q Now, if you were going to be consulted by a client for that very problem, okay, somebody says we think there was adulterated product, but all the testing that's been done shows that the product is within specs, what would be your next step to figure out whether there was in fact bad product in order to remove the doubts and wonderings?

A I would say to them why do you think you made adulterated product?

Q That's not what I'm asking you. You've been consulted. Okay?

A Right.

Q We know the FDA has done these 483s and the warning letters. Okay?

A Uh-huh.

Q But all the test results show normal Digitek. No one has come and shown you defective Digitek. What would be your next step as a consultant

to advise the company about whether there was in fact out-of-specification Digitek out in the market?

A I don't think that's the same question you asked me a minute ago.

Q Well, I think -- answer the one I just asked you.

A The question --

Q Answer the one I just asked.

A Give it to me again, please.

MR. MORIARTY: Read it back, Angela, please.

(The record was read back as requested.)

A What's the company asking me? I mean, what's -- I'm missing --

Q Mr. Farley, is there defective Digitek in the hands of consumers?

A Oh, your company.

Q Yeah. Not is it adulterated. We want to know, because we've got all these good test results, is there defective Digitek in the hands of consumers? What do you do as a consultant?

A I want to review all your procedures, every procedure, your lab testing, your manufacturing. I want to see existing data. But you've just assured me existing data was good.

I want to verify that the methods were accurate, validated and that the personnel are trained. And then I want to look -- I want to watch you make a batch. I want to watch you test it.

Q Did FDA ever cite, warn or observe that Actavis didn't have validated methods for the production and testing of Digitek?

A They said they weren't using certain methods, that methods that were supposed to be used were not being used. Whether they cited for any being not validated, I'm not sure. There may have been. I'm just not sure. But I do know they said you had procedures, you weren't using them.

Q Any that specifically involved the actual quality of the end product?

A Anything in manufacturing involves quality of the end product. So my answer is yes.

Q Okay. So in your mind if somebody put a label on upside down -- which would be a GMP violation, wouldn't it --

A Yes.

Q -- that is -- that means it's likely that that product is out of specification?

A It means you don't know anything about that product. It means what are you going to do about

it. You've got to take that product, that big drum or whatever it is, and test it to be sure that what you think it is is really what it is.

Q Okay.

A You can't --

Q Well, it passed finished product testing, Mr. Farley. So are you telling me that in your mind the upside down label means that that product is out of specification?

A No. It means they're -- it means you have to look more into it. There's a possibility it may be. Upside down label, you don't know what's there. Whatever the label says, you don't know what's in that drum.

So you have to do a tracking of how whatever it is got there, plus you've got to do some more testing here and now before you do anything with that.

Q Okay. Did FDA ever cite, warn or observe that Actavis employees were not properly trained in manufacture of Digitek?

A I did not read anything to that effect.

Q If the -- if Actavis was consistently producing double thick tablets, is it more likely than not that it would have been detected either by pharmacists filling prescriptions, consumers taking

prescriptions or UDL when it was packaging the product in blister packs?

A Consistently, that's a somewhat vague term. But if you mean daily with batches that go out, it is likely that someone somewhere would have caught it. It's also likely that some people would have ingested it and either died or had some serious medical problems.

Q All I'm asking you is whether it's likely it would have been detected and that is the look, correct?

A Oh. I was just saying before or after the fact. It's likely it would have been defected. When I don't know.

Q All right. Do you know -- do you know how many -- do you know how many Digitek tablets were recalled?

A A figure -- or not -- no. 4.8 million, that's a batch. Many, many millions. I don't know the exact number offhand.

Q Okay.

A Tablets you're talking about?

Q Yeah.

A Okay. Many, many millions.

Q Like 688 million?

A That wouldn't surprise me.
Q Do you know how many of the recalled batches were .125 versus .250?
A Not offhand.
Q Do you know what percentage -- do you have an opinion to a probability what percentage of the recalled Digitek was defective by being out of specification low?
A Out of specification low?
Q Yes.
A I do not --
MR. ERNST: Objection to form.
A -- have any knowledge to that effect.
Q Do you have an opinion to a probability?
A No.
Q Do you have an opinion to a reasonable degree of probability as to what percentage of the recalled Digitek was defective by being out of specification on the high side of the API?
MR. ERNST: Objection to form.
A No, I don't have an opinion or any knowledge of that.
Q If there were out-of-specification Digitek with the API on the high side, above its specifications, do you have any opinion to a probability as to how high

those were?

MR. ERNST: Objection to form.

A If they were out on the high side do I have an opinion how high they would be?

Q Yep.

A No.

Q Do you have an opinion as to how many double thick tablets were released to the marketplace between 2006 and 2008?

A I do not.

Q Do you have an opinion to a reasonable probability as to how many normal sized tablets with too much API were released to the market?

A I do not.

Q Given what you have told me so far I assume you have no opinion to a probability as to how many out-of-specification tablets may have made it into a particular patient's prescription vial, whether they got one or whether they got none, whether some people got tend out of thirty.

Do you have any opinions to a probability on that?

A No opinion as to a probability.

MR. MORIARTY: How we doing on time, Bill?

THE VIDEOGRAPHER: We have thirteen minutes, sir.

MR. MORIARTY: Okay.

BY MR. MORIARTY:

Q All right. Flipping through notes, some of these I've already asked you, so -- I think you said in your first deposition you said something about somebody dying from Digitek eight to ten years before the recall.

Do you know where you got that information?

A I mentioned something that I had heard or read that a person had died. And I think it was Mr. Anderton who put it in the proper perspective and mentioned when.

The other part of your question was where did I get that. I am not sure. It might have been Pete Miller telling me or in a conversation. But it was something like that.

Q Do you have any scientific basis to know whether people taking normal doses of Digoxin can have toxicity and die as a result?

A No. That would be more for an M.D. and I'm not a physician.

Q And you haven't read the depositions of Dr. Semigran or Ph.D. Nelson from Cincinnati in this

litigation?

A No, neither of them.

Q So you don't know whether that came from an adverse event report that was in your material or some anecdotal piece of information?

A I don't know that -- what was in the adverse --

Q This thing about somebody dying eight to ten years before.

A I don't know.

Q Okay. Are you an expert in statistics?

A No, I'm not an expert in statistics. I know a little bit, but not an expert.

Q Do you know what level of testing of a product would rise to the level of statistical significance or would you defer to a statistician on that?

A I would defer to a -- I would have an idea, but I would defer to a statistician to look for the traditional 95 percent probability of this occurring rather than that.

Q Okay. Now, this statement about a total failure of the quality systems --

A Yes.

Q -- if somebody were to assume that there

was a total failure and that Actavis could not make Digitek within the specs, that would be an improper assumption, wouldn't it?

A I'm trying to think if it's the same that my thoughts are. I wouldn't trust anything they made after seeing that. But to say that a particular bottle is good or bad, I would have no way of knowing.

Q Okay.

A Did I answer your question?

Q Well, not exactly but I'm going to follow up.

A Okay.

Q If somebody said there was a total failure of the quality system, so we assume that Digitek could not have been made properly, that would be a wrong assumption, wouldn't it?

A If somebody said there was a total failure --

Q Yes.

A -- and --

Q And then assumed that Actavis could not make any Digitek properly, they would be wrong, wouldn't they?

A Well, if somebody told me there was a total failure I'd say, tell me why you say that, why are

you saying a total failure. Then I would want to hear all the various reasons that made them use that term. Then I would pass judgment.

Q I'm asking you a simple question. Okay? If somebody said there's a total failure of the quality system and then they assumed that Actavis could not make Digitek within the specs, from what you know and what you've even seen today that would be a wrong assumption, wouldn't it?

MR. ERNST: Objection.

A On the samples that were tested those samples were good. So it would be an erroneous assumption to say that everything that came out was bad.

Q Okay. Thank you. Now, let me make sure I understand something you said in your deposition -- your first session of your deposition. We had 70924 with the 20 double thick tablets, correct?

A Yes.

Q You remember that?

A I remember that.

Q And I got the impression from what you've said earlier that if somebody showed you the preceding batch and the trailing batch after 70924 and they were fine and within the specs during production and finished product testing, that you would consider something like

70924 to be an isolated incident.

Do I understand that correctly?

A I need more batches. No, no, not just the one before or the one after. Maybe the five or ten before and the five or ten after.

Q Okay.

A I need more than just what you said to have me look at that I say potentially isolated incident.

Q All right. Did you ask for any specific number of preceding or trailing batches in this case?

A I believe my words were something to the effect of give me whatever you can get before and after.

Q And did you get anything other than 70924?

A No, sir.

Q So as it stands right now you don't know whether that was an isolated incident. Is that fair?

A Whether the findings of the 20 double thick tablets were isolated?

Q Yes, sir.

A I do not know if that was or was not an isolated incident.

MR. MORIARTY: Okay. Let's go off the record. I want to take five minutes with my colleague to see if I am finished and then she can

ask questions if she wants.

THE VIDEOGRAPHER: All right. Off record, 12:25 p.m.

(A brief recess was taken.)

THE VIDEOGRAPHER: We're back on record. This is the beginning of Media Unit No. 4 and it is 12:49.

BY MR. MORIARTY:

Q Okay. Mr. Farley, I just have two things to do. One is housekeeping. Okay? This is Exhibit 74C. It is the latest version of the notice for this deposition. Okay?

A Yes.

Q The first notice of deposition was marked as an exhibit in your last session. Do you remember that?

A Yes.

Q The big difference between this one and that one basically says that you are to bring with you all additional documents that you reviewed.

A Yes.

Q I asked you in the beginning of your deposition whether you had reviewed additional documents and you said you had not; is that correct?

A Yes.

Q All right. So let me ask you my final question just to make sure that I can understand how you got to a conclusion. Okay?

A Yes.

Q If somebody concluded, like you, that there was likely out-of-specification product in the marketplace, they could reach that conclusion in one of two ways. Okay? One is to read the regulatory documents and reach that conclusion, right?

A The 483s?

Q Yes.

A Yes.

Q And that's the way you reached your conclusion, correct?

A Yes.

Q Another way would be to read the results of scientific tests or reports that people had measured out-of-specification tablet in the field. That would be a different way to reach that conclusion, correct?

A I wouldn't reach the same conclusion.

Q I'm not asking whether you reached that conclusion. That would be another way to reach that conclusion if in fact that it occurred, right?

A The conclusion that there was a high probability?

Q You told me --
A They're different things. A sample is a sample, but the --
Q Can you listen to the question --
A I'm listening.
Q -- please? Don't read too much into the question. Okay? You've reached the conclusion that there was likely defective Digitek in the marketplace, right?
A Yes.
Q You reached that conclusion through the regulatory documents, the 483s, the warning letters and a consent decree, correct?
A Yes.
Q You did not reach that conclusion by reading reports of scientists who had observed, measured or tested out-of-specification Digitek in the marketplace, correct?
A Correct.
MR. MORIARTY: Thank you. I'm done.
MS. DONAHUE: Are you ready?
THE WITNESS: Any time.

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CROSS EXAMINATION

BY MS. DONAHUE:

Q Good afternoon, Mr. Farley.

A Yes, ma'am.

Q I introduced myself off the record. I'm Alicia Donahue. I'm with Shook, Hardy & Bacon in San Francisco and I represent the Mylan entities, as we call them, Mylan defendants, and UDL Labs in this case.

A Yes.

Q And one follow-up question to the deposition notice that I wanted to make sure we covered was in regard to that notice and the documents that you were requested to bring with you today pursuant to the second deposition notice, did you bring any new documents today to the deposition that weren't produced by you either physically or by virtue of the thumb drive at your original deposition back in July?

A My time log where I log in what day and how many hours I worked for Meghan.

Q That's been updated since your last deposition?

A It's last week. It just essentially is last week.

Q Could we get a copy of that?

A Yes. I have it on the thumb drive over there.

THE WITNESS: And, Meghan, I gave that to you last night.

A I mean -- excuse me. And I gave it to Meghan last night, yes.

MS. DONAHUE: Can we just agree, counsel that, you will --

A One is a time log and the other is an activity chart that says more what I did and the time log says when I did it so that it tells me I did what I was supposed to do and I know how much time to --

Q I appreciate that.

A -- how much time.

Q Thank you.

MS. DONAHUE: So, counsel, are we in agreement we can get a copy of that?

MS. CARTER: Yes.

MS. DONAHUE: Thank you.

BY MS. DONAHUE:

Q Okay. And now, very quickly, I believe, Mr. Farley, you in regard -- in response to one of Mr. Moriarty's earlier questions, I believe you testified that the purpose of your report in this case was to provide the opinions that you plan to render at trial in this case; is that correct?

A Yes.

Q Okay. And I went through your report pretty diligently and I didn't see any mention of any opinions in regard to either the Mylan defendants or UDL Labs.

A Yes.

Q Nowhere in that report did you opine that Mylan or UDL -- did you opine in any regard on their conduct in regard to distributing Digitek?

A Correct.

Q And nowhere in that report did you comment in regard to Mylan or UDL's conduct in regard to any testing that any of those entities may have done in regard to Digitek?

A Correct.

Q As you sit here today, Mr. Farley, do you intend to offer any opinions at the trial of these cases in regard to Mylan or UDL's conduct in relation to its distribution of Digitek?

A I do not intend to.

MS. DONAHUE: Thank you. That's all the questions I have.

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CROSS EXAMINATION

BY MR. KERENSKY:

Q Sir, do you have -- excuse me. Sir, do

you have an opinion about whether or not it is probable, that being more likely true than not, that Actavis manufactured Digitek tablets that presented an unreasonable risk of serious bodily injury or death to consumers and that those tablets were actually distributed to the consuming public? Do you have an opinion about that based on reasonable probability and that being more likely true than not?

MR. MORIARTY: Objection.

Q Answer.

A I do have an opinion.

Q What is that opinion?

A It's my opinion -- and it is based on the 483s and the warning letters and the consent decree -- that in which the entire manufacturing and testing flow is shown to be completely inadequate and not in compliance with regulatory.

It is my opinion there's a very high likelihood that there may be what I call bad product out on the market and that consumers have a chance of being seriously injured.

MR. KERENSKY: Thank you. No further questions.

Any questions from you, Mr. Ernst? Did we start without him? Don?

MR. MORIARTY: It' snot my day to watch him.

MR. ERNST: Yes, I do. I've got some questions --

MR. KERENSKY: Go ahead.

MR. ERNST: -- if I can ask him.

MR. KERENSKY: Go ahead and ask him. It's your turn.

MR. ERNST: All right.

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CROSS EXAMINATION

BY MR. ERNST:

Q Is it more likely true than untrue that Digitek tablets that presented a danger to consumers, including the risk of injury and death, were manufactured and placed into the stream of commerce by Actavis?

MR. MORIARTY: Objection, asked and answered not 120 seconds ago. Go ahead.

A In my opinion it is true what you said, yes.

Q Is it more likely true than untrue that Actavis failed to provide adequate quality control over the Digitek tablets that it manufactured?

A It is more likely true.

Q Is it more likely true than not true that out-of-specification Digitek tablets were manufactured and distributed by Actavis?

A It is more likely true. I believe that.

Q Is it more likely true than untrue or more probably than not that Digitek tablets that presented a danger to consumers, including the risk of death, were actually placed into the stream of commerce and were received by consumers based upon the information and the documentation that you have reviewed to date?

A In my opinion it is more likely true.

Q Is it your opinion that based upon your training and experience that documents that you have reviewed, all of the reading material that you are aware of to date that Digitek tablets that were manufactured by Actavis presented a risk of harm to consumers?

A Yes.

Q And is it your opinion that because of this risk of harm to consumers that Digitek tablets were recalled?

MR. MORIARTY: Objection.

A Say again, please.

Q Sure. Is it your opinion and is it more likely true than untrue that based upon the material that you have reviewed that the Digitek tablets were

recalled because they presented a danger to consumers, including the risk of death?

MR. MORIARTY: Objection.

A Yes.

MR. ERNST: Thank you. I have nothing else.

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REDIRECT EXAMINATION

BY MR. MORIARTY:

Q I have a follow-up question for you.

A Yes, sir.

Q Now, you've heard Mr. Ernst over the telephone ask you some questions. Does his voice sound familiar?

A He was on speaker last night in here.

Q Okay. Did Mr. Ernst tell you that in his specific case tablets from his client's prescription were tested by NMS Laboratories and found to be within the Digitek specifications?

A No.

Q Okay. Is that kind of information important to you in rendering opinions in a case like this?

A All information such as that is important, some more or less.

MR. MORIARTY: Okay. Thank you. That's all I have.

MR. KERENSKY: Let's wrap it up. Head for the airport.

THE VIDEOGRAPHER: All right. That concludes the deposition of James Farley. It is 12:59 p.m this is the end of Media Unit No. 4. Thank you.

(Off the record discussion was had.)

MR. MORIARTY: As you know from previous deposition experience you have the right, if you wish, to read and sign the transcript when it is prepared and distributed --

THE WITNESS: Yes.

MR. MORIARTY: -- to make sure that she typed complicated words properly, spelled them, got everything you said, et cetera. Okay?

THE WITNESS: Yes.

MR. MORIARTY: Or you can waive that right, trusting that she's an excellent court reporter with obvious long-term experience in this and never had to stop us to ask us anything. It's up to you.

THE WITNESS: With all due respect to Angela, I would like to read it.

MR. MORIARTY: Fine.

(The proceedings were concluded at 1:00 p.m.)

CERTIFICATE

GEORGIA:

CHATHAM COUNTY:

I, Angela S. Garrett, Certified Shorthand Reporter for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the witness was duly sworn to testify to the truth, the whole truth, and nothing but the truth; that the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed by computer-aided transcription; that the foregoing deposition, as typed, is a true, accurate, and complete record of the testimony of the witness and of all objections made at the time of the examination.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 24th day of January, 2011, at Savannah, Chatham County, Georgia.

_____

Angela S. Garrett, CSR, RPR

D I S C L O S U R E

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Date: January 24, 2011

Angela S. Garrett
RPR, CCR-B2407

Q